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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 10 March 2004 with an application for Letters Patent number 531703 made by SOMAR TECHNOLOGIES LIMITED.

Dated 8 July 2005

Neville Harris
Commissioner of Patents, Trade Marks and Designs

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531703

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Patents Act 1953

PROVISIONAL SPECIFICATION

ORTHOTIC DEVICE

We, **SOMAR TECHNOLOGIES LIMITED,** a New Zealand company, of Level 27, 151 Queen Street, Auckland, New Zealand do hereby declare this invention to be described in the following statement:

PT043966418

Orthotic Device

Field of the Invention

This invention relates to Patello-femoral Orthoses.

Background

Patello femoral bracing is used to treat conditions of the patello-femoral joint. This is the joint between the patella and the anterior femoral condyle just proximal to the knee. The patella is a sesamoid bone in so far as it lies within a tendon; namely the quadriceps tendon. Its function is to act as "pulley" for the tendon as it crosses the knee joint. Because the patella lies in the tendon, its position relative to the anterior femoral surface is determined by the line of pull of the quadriceps, and by the structures which assist in holding it in the femoral groove throughout the range of motion. The most common cause of patello femoral pain is mal-tracking of the patella.

Any mal-tracking can occur during flexion or extension, more commonly in mild cases, during extension, and more commonly in severe cases during flexion.

Buttresses of various shapes have been used to help stabilise the patella. Most surround the edges of articulating portion the patella as the superior pole or top portion does not articulate and is completely encapsulated by tendon, so a buttress can have little effect.

Most mechanisms are designed to exert a uni-directional force on the patella in the medial-lateral direction throughout knee movement such that lateral movement or "lateral drift" which leads to subluxation or dislocation is prevented.

However, the tracking of a patella in any individual can vary quite considerably. Rather than moving in a linear up and down motion or medial and lateral motion, the patella tends instead to "snake" its way in a general up and down direction throughout the range of knee motion. This is determined by the relative forces exerted by the quadriceps, the supporting structures, and the shape of an individuals articular surfaces within the patello-femoral joint.

Object

It is an object of the present invention to provide an orthotic device which will at least go some way toward overcoming disadvantages of existing constructions, or which will at least provide the public with a useful alternative.

Summary of the Invention

In one aspect the invention broadly provides an orthotic device including a pressure cuff adapted to apply a force to a patella to assist proper tracking of the patella during movement of the knee, and adjustable means for maintaining the cuff in a required position relative to the patella and for applying a required force to the patella in a medial - lateral direction and in an inferior - superior direction.

Preferably aresultant force may be applied to the patella in any resultant direction in the medial-lateral plane or the inferior-superior plane.

Preferably the device includes an upper substantially rigid arm and a lower substantially rigid arm, the arms being hingedly interconnected so is to move rotatably relative to each other during movement of the knee, and the adjustable means being connectable directly or indirectly to the upper arm and the lower arm.

Preferably the device includes a flexible sleeve supported by the arms, the sleeve being adapted to locate about the knee of the user.

Preferably the sleeve includes a buttress adapted for location about a periphery or a peripheral portion of the patella.

Preferably the cuff is located in use about an exterior surface of the buttress, so as to apply a force to the buttress, and therefore apply a force to the patella.

Preferably a further upper arm and a further lower arm which are hingedly interconnected our provided for location on opposite side of the knee.

Preferably the cuff includes at least three connection members, one connection member being connected to one side of the sleeve and two connection members being connected to the other side of the sleeve, one being connected above the hinged engagement and the other being connected below the hinged engagement.

Alternatively the cuff includes four connection members, one connection member being connected directly or indirectly to each of the four arms.

Preferably the position of the engagement of at least some of the connection members is adjustable to thereby adjust the force applied to the patella.

Preferably the connection members comprise adjustable straps. Preferably the straps are resilient or elastic.

Preferably the arrangement of the connection members and the arms or sleeve is such that a desired force or change in force can be applied to the patella during flexion of the knee, and the force or change in force can be applied in a desired direction or range of directions.

Preferably a chafe is provided to enable each connection member to engage with an arm or sleeve.

Preferably each chafe includes a pin which is adapted to be received in an aperture provided on the arm or sleeve whereby the chafe may rotate within a range of movement relative to the arm or sleeve.

Preferably the pin includes a heating having a shape which is selected to allow the chafe to be engaged in the aperture in a first orientation, but to be unable to be removed from the aperture when the chafe is in a second, operational, orientation.

Further aspects of the invention will become apparent from the following description.

Drawing description

One or more embodiments of the invention will be described with reference to the accompanying drawings in which:

Figure 1 is a front elevation of a knee brace

Figure 2 is a rear elevation of the brace of figure 1

Figure 3 is a side elevation of the brace of the preceding figures

Figure 4 is an elevation of one embodiment of a cuff

Figure 5 is an elevation of another embodiment of a cuff

Figure 6 is an exploded perspective view of the cuff of figure 5

Figure 7 is a perspective view from above of a chafe

Figure 8 is a perspective view from below of the chafe of figure 7

Figure 9 is an exploded perspective view of a chafe and arm

Figure 10 comprises perspective views of a chafe engaged with one or more arms

Figure 11 is a diagrammatic front elevation of a cuff engaged with arms

Figure 12 is a side elevation of another terms of embodiment of a cuff

Figure 13 is a rear elevation of the cuff of figure 12

Figure 14 years a perspective view from the front of the cuff of figures 12 and 13

Detailed Description

Referring to the drawing figures, an orthotic device according to the invention is shown having two arms (10) and (12) that are hingedly connected together by a hinge assembly which is generally referenced (14). The arms (10) and (12) are, in the preferred embodiment, replicated on the other side of the device, so that a pair of arms connected by a hinge assembly is provided in use on either side of the knee of a person using the device. Those skilled in the art will realise that the invention could be effected without replicating the arms and hinge assembly on either side of the device.

The arms (10) and (12) are constructed from a substantially rigid material, for example an aluminium or a plastics material, or laminated materials including fibre reinforced materials or a combination of all the foregoing. The hinge assembly (14) can be constructed in a variety of different ways known to those skilled in the art to which the invention relates, and will typically be constructed using a rivet or pin to provide a pivot point that interconnects the adjacent ends of the arms and includes means limit the range of movement.

The arms (10) and (12) are provided within an appropriate structure for engaging

regions of the user's leg adjacent to the knee to enable the device to be securely attached to the user. Therefore, in the preferred embodiment a sleeve (16) is provided which is constructed from an appropriate material such as a neoprene or elastic foam material so that the device is securely and comfortably engaged with the user's leg within the vicinity of the user's knee. Those skilled in the art will realise that a number of different structures may be used to replace the continuous sleeve. To enable securement of the sleeve to the user, straps (18) and (20) are provided. These may include a connectable webbing material or hook and loop material such as VELCRO to facilitate tightening and engagement, but other fastening mechanisms such as buckles may be used. A region of the sleeve (22) can be replaced with a lighter material or removed altogether at the rear of the device in order to facilitate flexion.

The sleeve (16) includes a buttress (24) which is shaped and positioned to enable it to be located in use adjacent to the edge or periphery of the articular portion of the patella. The buttress may be formed from a variety of different materials, but in the preferred embodiment it is constructed from a resilient foam or plastics material. The buttress (24) substantially surrounds the articular portion of the patella in the preferred embodiment, but could be broken or segmented, or only surround a selected portion of the articular portion of the patella.

Referring now to Figure 3, the arms (10) or (12) (or a part of the sleeve or other structure attached to the arms) includes a number of connection points (25) to (27) which are shown in more detail in subsequent drawing figures, and these may take a variety of forms. In particular, these could in some embodiments comprise Velcro attachment points or buckles. However, in the most preferred embodiment the connection points are adapted to connect with chafes, such as chafes (30) (referred to Figure 4) provided on a cuff according to the invention.

Turning to Figure 4 (a cuff is shown generally referenced (32) and having a body (34) which is adapted to locate over buttress (24) in use so that a force may be applied to the buttress. The body (34) of the cuff can take a variety of forms, and in the embodiment shown in Figure 4 is substantially "horseshoe" shaped. To use the cuff shown in Figure 4, a user places attachment loop (36) over one of the hinges (14), then engages chafes (30) with a selected socket (25) to (27) of each of the upper and lower arms (10) and (12).

In the most preferred embodiment the cuff takes the form shown in Figure 5 in

which there are 4 connection straps, each strap having an engagement device such as a chafe (30) (not shown) for engagement with one of sockets (25) to (27) on each arm. The cuff (40) shown in Figures 5 and 6 may include a supra patella link (42). The body of cuff (40) is shown in exploded view in Figure 6, in which it can be seen that the body includes upper and lower parts (44) which include tabs (46) to which straps (48) are connected. The parts (44) are moulded to include a recess for location over an internal moulded foam structure (50) which in use is welded between the cuff members (44). The ends of straps (48) are connected between tabs (46) by stitching, welding or gluing or a combination of these attachment methods.

In Figures 7 and 8 the chafes (30) are shown which are in use connected to the ends of straps (48). The chafes include a buckle or ladder lock (52) which allows adjustment of the length of each strap. The chafe also includes an engagement pin having a head (54) which is shaped to engage with slots (56) (refer Figure 9) of each socket when the head is positioned in the correct orientation.

Figure 10 shows engagement of the head with a slot (56). As can be seen from that figure, each slot (56) is arranged so that swivelling or rotational movement of the chafe through the flexion/extension range of movement will not cause the chafe to adopt an orientation where it can be removed from the slot (56). Accordingly, a secure engagement can be made.

Use of the invention is as follows. A user firstly engages the device with the leg such that the internal surfaces of the buttress are adjacent to the periphery of the articular portion of the patella. Then the pressure cuff (40) (or 32) is placed over the buttress. The invention will be described with use of pressure cuff (40), however it will be seen that other forms of cuff that are adjustable in multiple planes may also be used, for example cuff (32).

The attachment straps (48) of the cuff (40) are adjusted in length, and in their point of fixation to enable the cuff to be located in the correct position over the buttress and to exert a desired force during the flexion/extension movement of the user's leg. In order to assist with applying an appropriate force, the straps (48) may be constructed of a resilient or elastic material.

It will be seen that the further they strap is connected from the hinge, then the longer the

resultant lever arm, and thus the greater the force that will be applied as the degree of flexion increases. This concept may be used to provide considerable variation in the magnitude of the force applied to the patella. Furthermore, by selecting the degree of elasticity or resilience each connection member, greater control can be provided over the force which is applied.

For example, the straps could be adjusted for maximum tension at 30 degrees of flexion, if this is the point at which it is believed that the patella deviates in its tracking. Therefore, as flexion occurs from the fully extended position, an increasing force will be applied to the patella until the 30 degree position is reached.

Therefore, if connection members that are constructed from the same material are located at the same connection points along the arm or sleeve, then the force applied to the patella will increase during flexion, but the forces will be balanced, so the resultant force will be applied a posterior direction (ie to ward the rear of the knee).

However, if one connection member, for example, is connected to the sleeve or arm at a point further away from the hinge than the remaining connection members, then the force applied to the patella in the direction of that connection member will increase more relative to the force applied by the other connection members as flexion occurs. Accordingly, corrective forces can be customised to provide specific solution to the mal-tracking of an individual's patella. This is shown in figure 11 in which can be seen that the connection member indicated by arrow (60) is engaged with socket (27), whereas the remaining connection members are engaged with socket (25) of their respective arms. Therefore, as flexion occurs, they will be an increasing force applied to the patella in the direction of connection member 60 i.e. in an inferomedial direction. It will be seen that a particular angle of flexion may be chosen at which to engage and adjust the connection members. In this way, the magnitude and direction of the applied force can be selected at that particular angle of flexion, and the adjustment may be such that as the degree of flexion increases or decreases from that selected point, the magnitude and direction of the applied force can be varied by appropriate selection of the adjustment points to which the connection members have been engaged.

In selected embodiments of the invention, the connection straps, and other straps such as engagement straps (18) and (20) may be constructed from elasticised connectable material such as hook and loop material sold under the trade mark VELCRO

which has been modified by being provided with a limit to the degree of allowable elastic deformity i.e. by limiting the degree of stretch. This maybe effected in a number of different ways. In one example, the material may be stitched in a selected pattern, such as a zigzag pattern the angle of which is chosen so that the threat will straighten at a predetermined point and therefore that further elastic deformity. In another example, an inelastic material may be loosely attached to the webbing or hook and loop material at selected points to thereby limit the degree of deformity. We have found that limiting the degree of elastic deformity can be advantageous.

In another embodiment the cuff (40) may be constructed from a resilent or elastic material such as a thermoplastic elastomer or thermoplastic rubber. Such material may have one or more of the following properties:

Hardness	2-45 (Shore A)
Specific Gravity	0.85-0.95 (gm/cubic cm)
Tensile Strength	5-60 (kg/square cm)
Elongation at Break	1100-650 (%)
Tear Strength	30-50 (kg/square cm)
Brittle Temperature	minus 30 – minus 60 (degrees C)

An embodiment constructed (for example by moulding) using such a material is shown in figures 12-14 in which the cuff is referenced (70) and includes connectors (72) for connecting to straps (not shown) so that the cuff may be used as described with reference to cuff (40).

It will be seen that, by adjusting for points of fixation of the cuff to the remainder of the device, forces of selected magnitude may be exerted on the patella in a number of different directions, for example in a medial direction, an inferior (downward) direction, or a combination of these to varying degrees. Accordingly, true multidirectional and/or multiplanar control is provided. It also be seen that, the direction and magnitude of the force may be varied depending upon the degree of flexion.

It will also be seen that the apparatus can be set up at any point in the flexion – extension cycle so that the multidirectional or multiplanar force can be made to vary over a selected range of the cycle. Therefore, a user may use the brace for specific activities which involve movements concentrated in one range of the flexion – extension cycle.

Where in the foregoing description, reference has been made to specific components or integers of the invention having known equivalents then such equivalents are herein incorporated as if individually set forth.

Although this invention has been described by way of example and with reference to possible embodiments thereof, it is to be understood that modifications or improvements may be made thereto without departing from the scope or spirit of the invention.

It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be covered by the appended claims or (included within the present invention)

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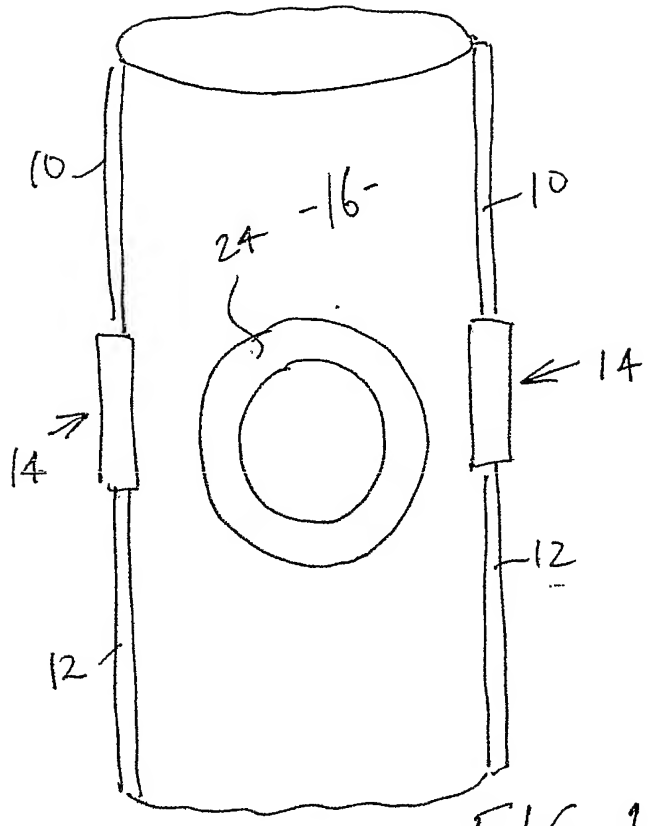


FIG 1

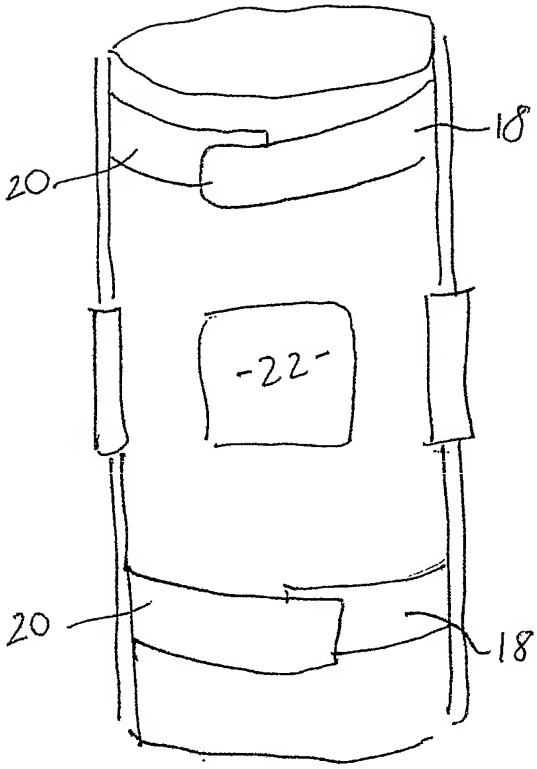


FIG 2

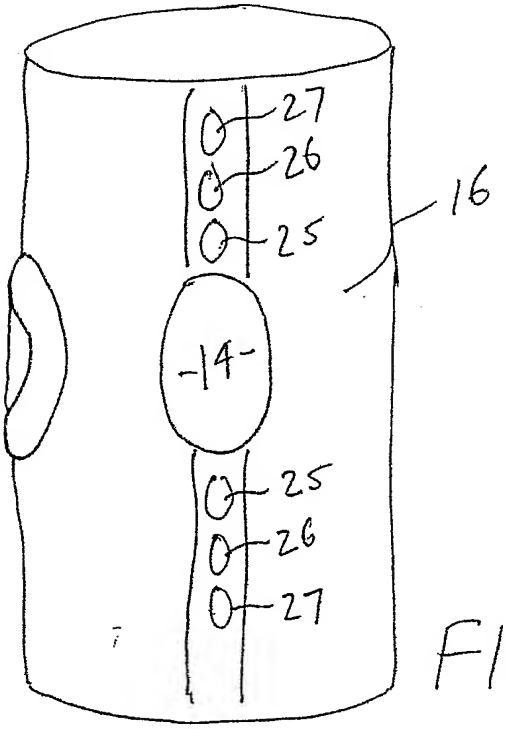


FIG 3

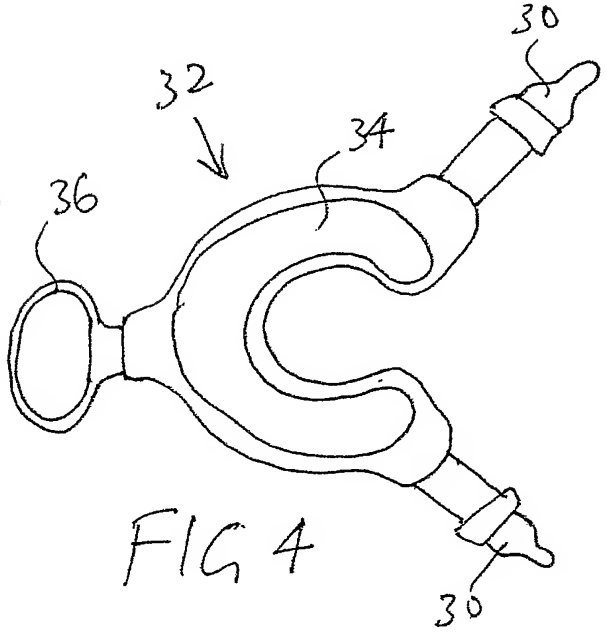


FIG 4

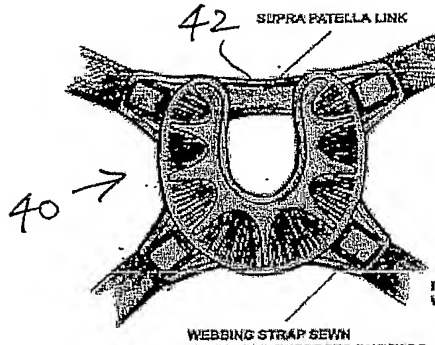


FIG 5

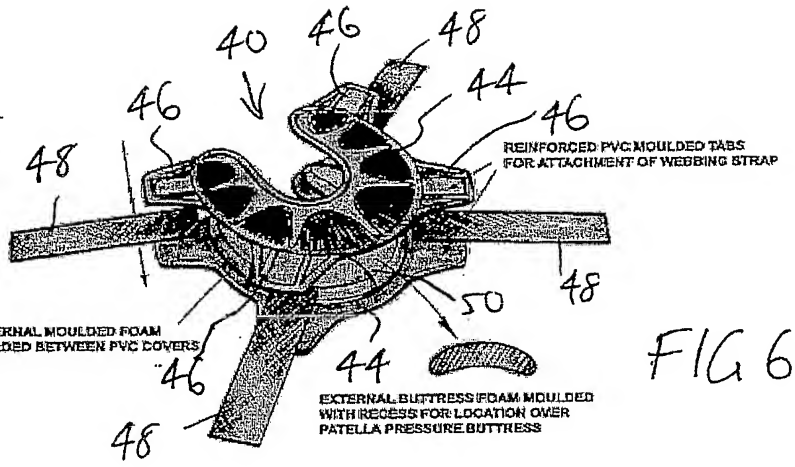


FIG 6

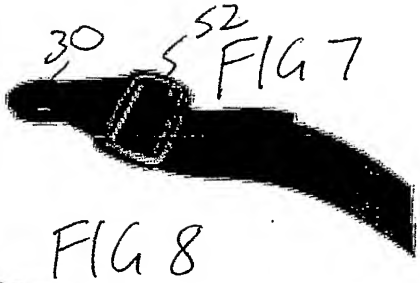


FIG 7

FIG 8

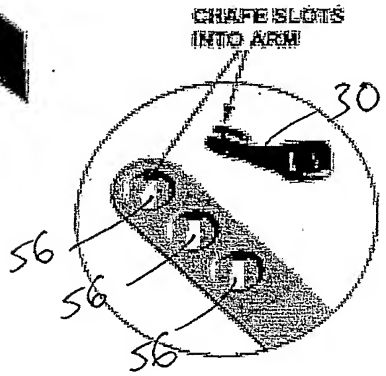
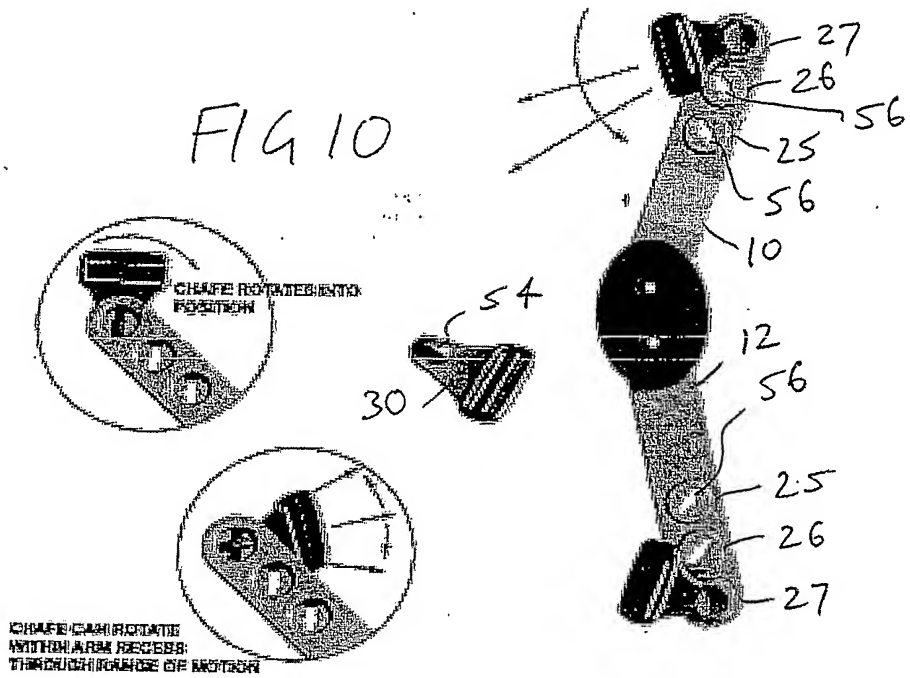


FIG 9

FIG 10


27
26
56
25
56
10
54
30
12
56
25
26
27
CHUCK ROTATED INTO POSITION
CHUCK CAN ROTATE WITH ARM RECESS THROUGH RANGE OF MOTION

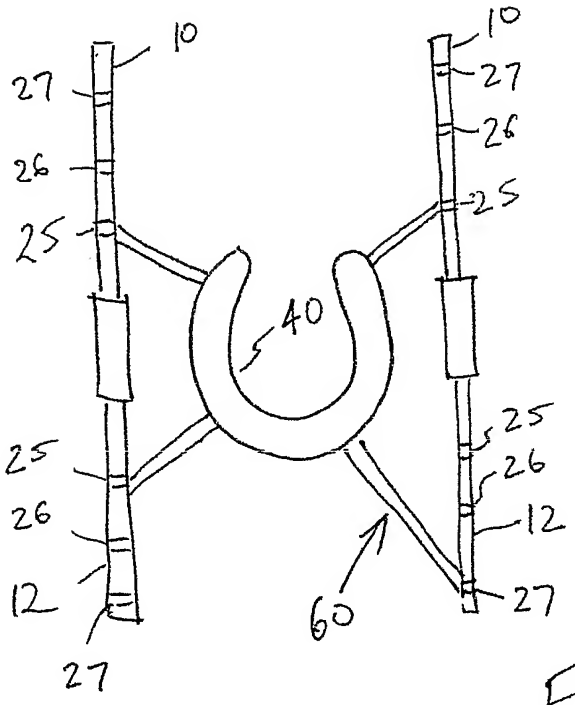


FIG 11

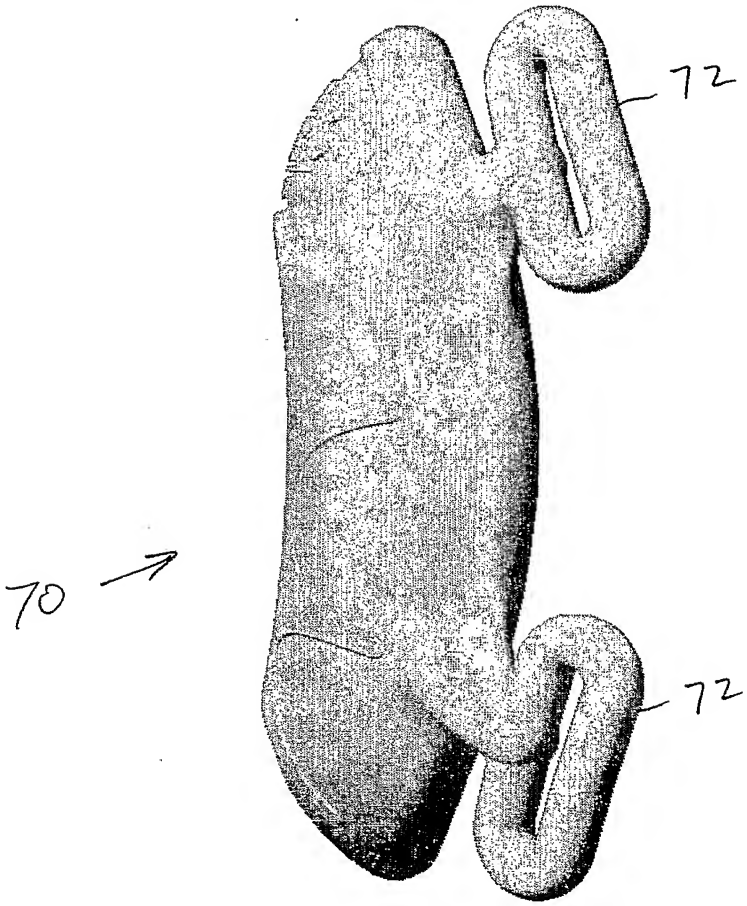


FIG 12

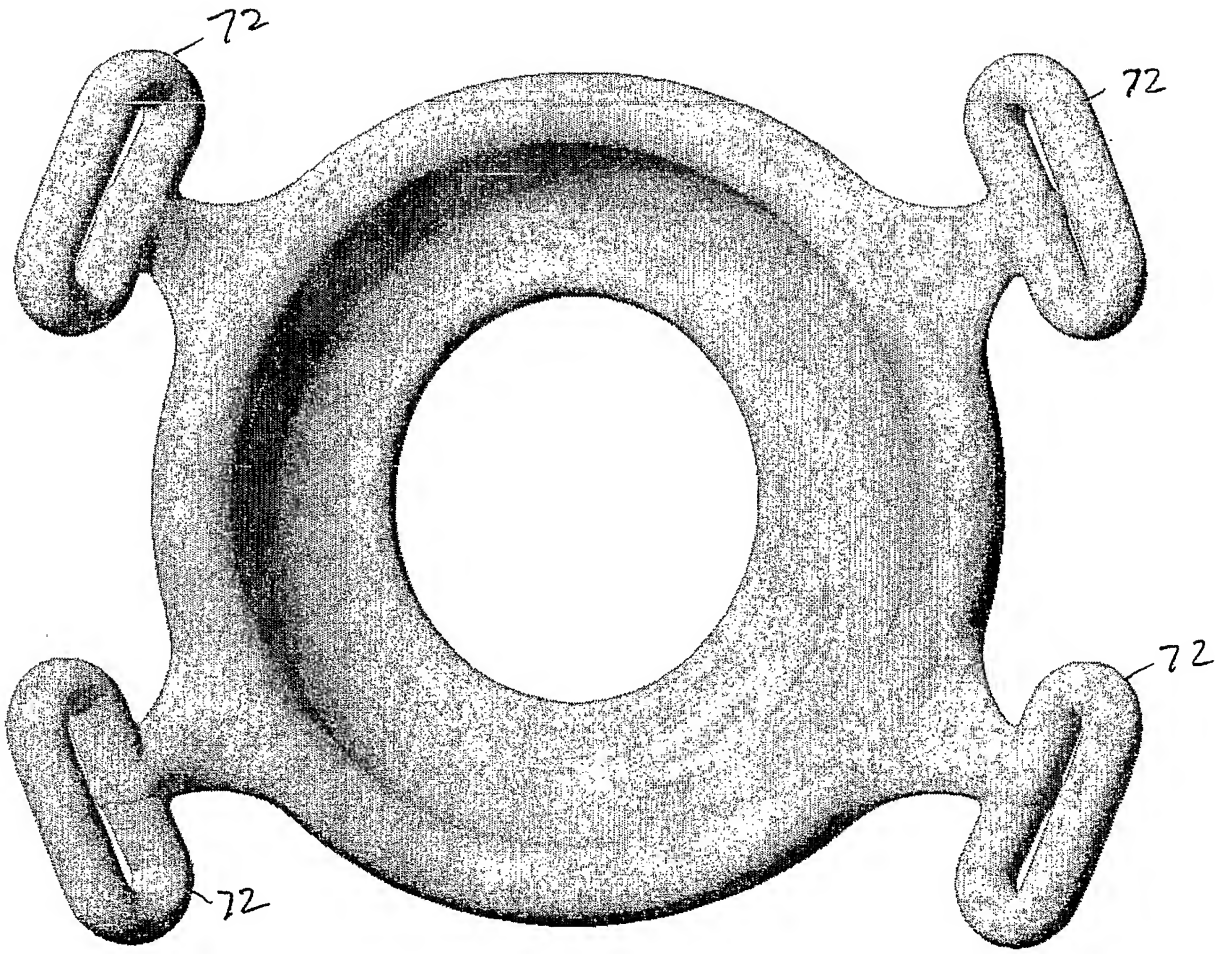


FIG 13

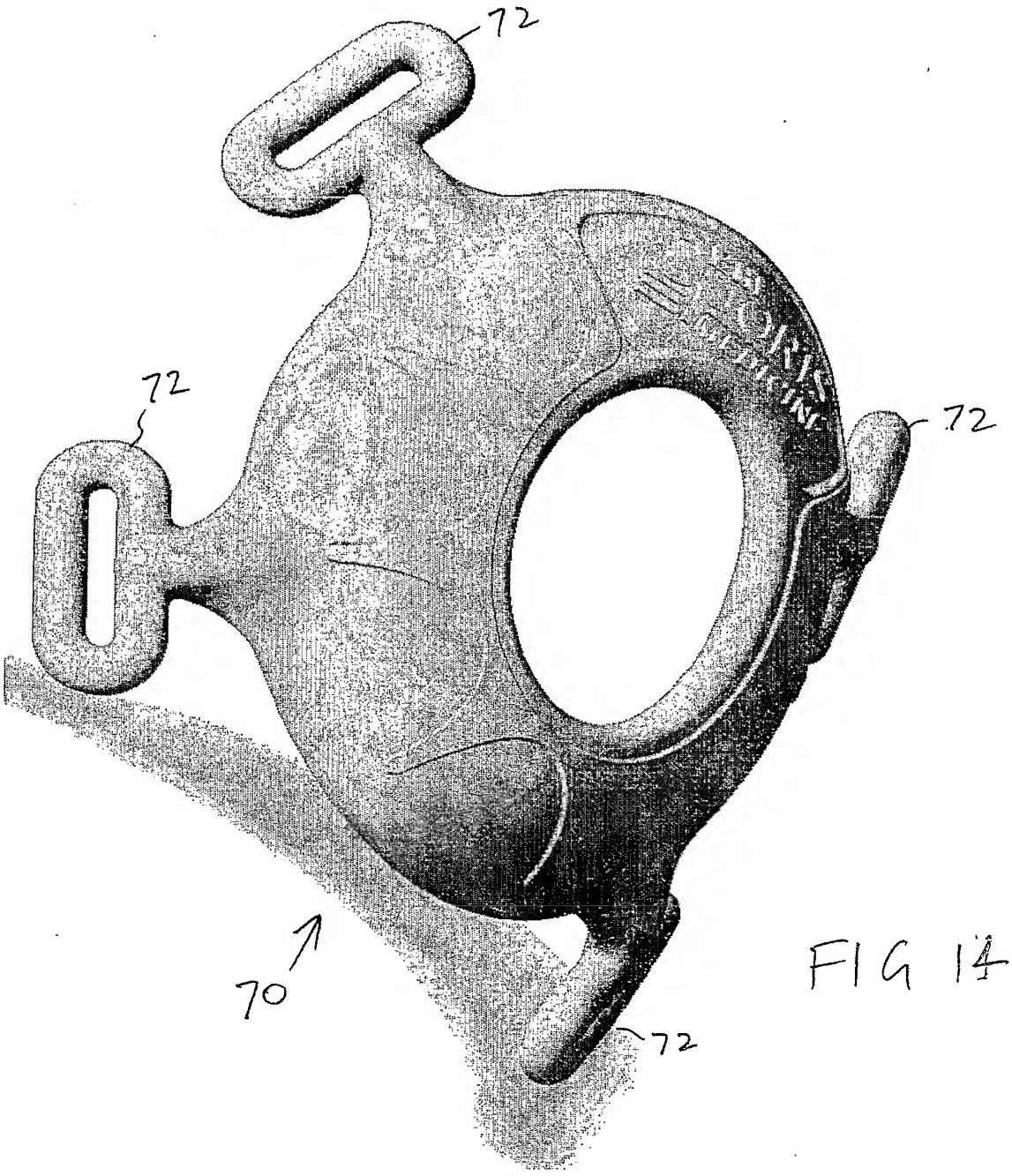


FIG 14